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10/780,155	02/17/2004	Wei-Kung Wang	LELI 3509	1279

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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/780,155	WANG ET AL.	
	Examiner	Art Unit	
	KAREN E. TOTH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11 and 13-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-11, 13-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

2. Claim 18 is objected to because of the following informalities: The amendment to the claim has resulted in deletion of its parent claim. For the purposes of examination, the claim will be treated as though depending from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-11, 13-32, 38, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The

Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 38 recite the broad recitation "faster than 1 ms", and the claims also recite "greater than 1 MHz", which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

5. Claims 1, 7, 23, 28-31, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Kirsten (US Patent Application Publication 2005/0252607).

Kirsten discloses an apparatus for selectively moving hydrogen atoms in an aqueous solution to reduce the viscosity of the solution (paragraph [0026]) comprising an electromagnetic field generator switching faster than 1 MHz (paragraph [0023], [0032]), and an electrical connection for introducing the electrical field in a target (paragraph [0019]).The examiner notes that, though the claim calls for a "low impedance" device, Applicant has not provided any limits as to what constitutes "low" impedance, and, as such, any connection device may be considered to be low impedance.

Regarding claim 7, Kirsten further discloses generating an alternating field (paragraph [0019]).

Regarding claims 29-31, the language "for selectively moving hydrogen ions in an aqueous solution" is intended use language - neither the ions nor the solution have been positively recited, and Kirsten is certainly capable of moving ions in any aqueous solution; the location of said solution does not affect Kirsten's capability, and, as such, Kirsten is capable of moving ions in a solution located in a small tube in a machine or microcirculation.

6. Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Keusch (US 5354790).

Keusch discloses an externally applied medium comprising a low pH organic acetic or lactic acid solution that acts as an impedance-lowering interface between an electrode and a target comprising a biological fluid (column 2, lines 28-31; column 29, lines 50-55).

Claim Rejections - 35 USC § 103

7. Claims 1, 3, 4, 6, 7, 8, 11, 17, 32, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst (US Patent 6029090) in view of Fuhr (US 6542778).

Regarding claims 1, 3, 4, 8, 17, and 38, Herbst discloses an apparatus and method for selectively moving hydrogen ions in an aqueous solution (organism) comprising an electrical field generator (column 1, lines 24-34; element 10), a plurality of low impedance electrical connection electrodes for introducing the field into a target (elements 30; column 6, lines 1-2), a monitor for measuring variations in an applied

current (column 9, lines 44-47), and means for determining a pH value from the generator's current (column 2, lines 27-30; column 3, lines 33-40). Herbst discloses the generator providing a field that switches, but does not disclose a particular switching rate or applied frequency. Fuhr teaches a system for providing an electrical field to a target where the applied frequency is greater than 1 MHz (abstract; column 4, lines 31-33), in order to provide effective stimulation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Herbst with a frequency of greater than 1 MHz, as taught by Fuhr, in order to provide effective stimulation. The examiner notes that, though the claim calls for a "low impedance" device, Applicant has not provided any limits as to what constitutes "low" impedance, and, as such, any connection device may be considered to be low impedance.

Regarding claim 6, Herbst further discloses generating step fields (elements 13, 17).

Regarding claims 7 and 11, Herbst further discloses generating an alternating field comprising a biphasic square wave (column 4, lines 47-54).

Regarding claim 32, Herbst further discloses measuring temperature with electrodes (column 9, lines 44-54).

8. Claims 5, 9, 10, 13-15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst in view of Fuhr, as applied above, and further in view of Palti (US 2004/0068296).

Regarding claim 5, Herbst in view of Fuhr discloses all the elements of the claimed invention, as described above, except for using the ion movement to generate heat. Palti teaches a similar device for selectively moving hydrogen ions in an aqueous solution where the ion movement generates heat (paragraph [0016]), since that is the natural physical result of application of high frequency fields to tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Herbst in view of Fuhr with the ion movement generating heat, as taught by Palti, since that is the natural physical consequence of such ionic movement.

Regarding claims 9, 10, 13, 14, and 19, Herbst in view of Fuhr discloses all the elements of the claimed invention, as described above, but does not disclose any particulars of the electrodes used in the device. Palti teaches using a plurality of electrodes (elements 230) to apply an electric field, where the electrodes may be placed on the target (figures 11, 14), arranged in pairs to generate fields across the target (figures 11 and 14), and being activated at different times (paragraph [0089]), in order to provide effective application of the field. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Herbst and Fuhr with a plurality of electrodes arranged on the target and/or in pairs, as taught by Palti, since Herbst and Fuhr did not provide any details as to the electrodes used with the device. The Examiner notes that, since the Applicant has not disclosed what the particular electrodes are to be considered “smaller” than, any electrode, including Palti's, may be considered to be of "smaller" area.

Regarding claim 15, Herbst in view of Fuhr discloses all the elements of the claimed invention, as described above, except for delivering the electrical field stimulation to a tumor. Palti teaches a similar device for selectively moving hydrogen ions in an aqueous solution by directing an electrical field at a tumor (paragraph [0021]), in order to provide treatment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Herbst and Fuhr and directed the field to generate ion movement in a tumor, as taught by Palti, in order to provide treatment.

Regarding claim 20, Herbst in view of Fuhr and Palti discloses all the elements of the claimed invention, as described above, except for the electrode pair generating electrode fields that add in terms of vector at the target. Palti teaches a similar device for selectively moving hydrogen ions in an aqueous solution by directing an electrical field at a target using electrode pairs, where the electrical field is inherently comprised of vectors, since the signals have magnitude and direction; when directed at a target (paragraph [0085]), a plurality of the signals would therefore add in terms of vector. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Herbst, Fuhr, and Palti with the electrical field generating electric fields that add in terms of vector, as taught by Palti, since vector addition is an inherent property of the electrical field.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst and Fuhr in view of Buchner (US Patent 6745078).

Herbst in view of Fuhr discloses all the elements of the claimed invention, as described above, except for the target comprising a region of poor blood circulation. Buchner teaches using electrical stimulation to increase blood flow in areas of poor circulation (column 2, lines 10-12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Herbst in view of Fuhr on an area of poor blood circulation, as taught by Buchner, since the use of electrical stimulation to increase blood flow is well known in the art.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst in view of Fuhr, as applied above, and further in view of Ostrow (US 2002/0147424).

Herbst in view of Fuhr discloses all the elements of the claimed invention, as described above, except for the device further comprising a monitor with an ultrasound-generating device. Ostrow teaches a similar device that applies electrical stimulation to promote ionization where electrical stimulation can be performed in combination with ultrasound (paragraph [0010]), in order to increase the device's efficiency. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Herbst in view of Fuhr with ultrasound, as taught by Ostrow, in order to increase the device's efficiency.

11. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst and Fuhr, as applied above, and further in view of Keusch.

Herbst in view of Fuhr discloses all the elements of the claimed invention, as described above, except for the low impedance connection device comprising a low pH lactic or acetic acid. Keusch teaches an externally applied medium comprising a low pH organic acetic or lactic acid solution that acts as an impedance-lowering interface between an electrode delivering electrical stimulation and a target comprising a biological fluid (column 2, lines 28-31; column 29, lines 50-55), in order to increase the effectiveness of the applied stimulation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Herbst and Fuhr with lactic or acetic acid in the connection device, as taught by Keusch, in order to lower impedance and increase the effectiveness of the applied stimulation.

Response to Arguments

12. Applicant's arguments filed 24 September 2008 have been fully considered but they are not persuasive.

Regarding claim 20, the Examiner notes that the claim was addressed in the previous action, though the paragraph was inadvertently labeled as being regarding claim 19. Since the subject matter of claims 19 and 20 is clearly different, Applicant should have noted the obvious error in claim identification. Further, claim 22 was clearly identified and addressed in the "Allowable Subject Matter" section of the previous action. Since all claims were addressed, this action is being made Final.

Regarding Kirsten, Applicant has not addressed any of the limitations cited by the Examiner, choosing instead to argue the relevance of a paragraph that was not cited.

The Examiner notes that application of an electromagnetic alternating field inherently produces the movement of hydrogen ions, especially when applied to an aqueous solution, as disclosed in Kirsten. Though Kirsten does not explicitly describe a generator, the disclosure that an electrical field is provided is an implicit disclosure of an electrical field generator.

Regarding Herbst, Applicant has argued that application of stimulus to a patient does not result in movement of hydrogen ions in an aqueous solution. The Examiner disagrees. A patient is inherently an aqueous solution and electrical stimulation inherently produces moving ions. Further, the language "for selectively moving hydrogen ions in an aqueous solution" is intended use language - neither the ions nor the solution have been positively recited, and Herbst is certainly capable of moving ions in an aqueous solution.

The rejections stand as final.

Allowable Subject Matter

13. Claims 21 and 22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the invention of claims 21, and 22, including, *inter-alia*, an apparatus for selectively moving hydrogen ions in an aqueous solution comprising an electron field generator that switches faster than 1 ms and a low impedance electrical connection device that introduces the field into a target

at a frequency greater than 1 MHz, where a current obtained from the generator is used to obtain a pH value and the value is subsequently used to estimate the possibility of a cancer.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yamamoto (US 4515162) and Thomsen (US 6845272), which disclose similar inventions.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735